UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

JOYCE BENEFIELD AND KERMOT BENEFIELD, Plaintiffs, -v- PFIZER INC., WYETH PHARMACEUTICALS INC., and John Does 1-50, Defendants.	:	14-CV-3394 (JPO) OPINION AND ORDER

J. PAUL OETKEN, District Judge:

In May 2012, Georgia resident Joyce Benefield sought treatment for a post-operative abdominal infection. She was prescribed Tygacil, an antibacterial drug manufactured by Pfizer and its subsidiary Wyeth Pharmaceuticals, for the infection. After she began taking the drug, Joyce says that she developed a number of conditions, including vasculitis, full-body lesions, organ and vessel damage, and hair loss. Joyce and her husband Kermot Benefield ("Plaintiffs") bring this action against Pfizer and Wyeth ("Defendants") in connection with those alleged injuries. They collectively assert claims for negligence, design defect, manufacturing defect, failure to warn, breach of express and implied warranties, fraud, unjust enrichment, and loss of consortium. They also seek punitive damages. Defendants have moved to dismiss the claims under Federal Rule of Civil Procedure 12(b)(6).

For the reasons that follow, Defendants' motion is granted in part and denied in part.

I. Factual Background[1]

A. The Injuries

Plaintiffs were, at all relevant times, married. (Dkt. No. 1, Complaint ("Compl.") ¶ 2.) They are residents of Douglasville, Georgia. (*Id.* ¶ 1.)

On May 2, 2012, Plaintiff Joyce Benefield underwent an exploratory laparotomy.[2] (*Id.* ¶ 21.) As a result of the procedure, Joyce developed a "post-operative abdominal wound infection" and was admitted to the hospital for treatment on May 11. (*Id.* ¶ 22.) She was prescribed Tygacil, an antibacterial drug, for the infection. (*Id.* ¶¶ 13, 23.) Joyce was discharged from the hospital on May 14, 2012, but was instructed to continue receiving Tygacil infusions at home. (*Id.* ¶ 24.) She did so until May 24, 2012. (*Id.* ¶ 25.)

About two weeks later, Joyce began to develop a set of serious medical conditions. On June 8, Joyce "sought medical attention for abdominal pain and a rash on her lower extremities." (*Id.* ¶ 26.) Soon thereafter, her rash "evolved into painful, blister-like lesions," which "spread to her stomach, arms, legs and feet" and ultimately to her entire body. (*Id.* ¶¶ 27–28, 30.) On June 14, Joyce was diagnosed with "vasculitis syndromes of the central and peripheral nervous systems." (*Id.* ¶ 31.) She alleges that "[h]er pain was a constant and [that] she was confined to a bed for a period of time." (*Id.* ¶ 33.) She also experienced organ damage, vessel damage, scarring, severe nerve pain, open and draining sores, and hair loss. (*Id.* ¶ 34.) All these conditions, Plaintiffs allege, resulted from Joyce's use of Tygacil. (*Id.*)

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[1] The facts below are, unless otherwise noted, drawn from the Complaint, and are accepted as true on a motion to dismiss brought pursuant to Federal Rule 12(b)(6). *Aegis Ins. Servs., Inc. v. 7 World Trade Co., L.P.,* 737 F.3d 166, 176 (2d Cir. 2013).

[2] A laparotomy is a "surgical incision into the abdominal cavity." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1005 (32 ed. 2012).

B. Tygacil

Tygacil, Plaintiffs allege, is a "tetracycline-class antibacterial drug" designed, manufactured, labeled, marketed, sold, and distributed by Defendants. (*Id.* ¶ 6.) It is administered intravenously. (*Id.* ¶ 14.) Its active ingredient is tigecycline. (*Id.* ¶ 15.) Tygacil is commonly used to treat infections, including "complicated skin and skin structure infections, complicated intra-abdominal infections, and community-acquired bacterial pneumonia" in individuals at least 18 years of age. (*Id.* ¶¶ 6, 17.)

On December 15, 2004, Wyeth submitted a New Drug Application ("NDA") for Tygacil to the Food and Drug Administration ("FDA"). (*Id.* ¶ 12.) The FDA approved an amended version of the NDA on June 15, 2005. (*Id.* ¶ 13.)

Plaintiffs allege that, in July 2010, the "Warnings and Precautions" section of Tygacil's label was updated to include the following information:

> An increase in all-cause mortality has been observed across Phase 3 and 4 clinical trials in TYGACIL-treated patients versus comparator-treated patients. In all 13 Phase 3 and 4 trials that included a comparator, death occurred in 4.0% (150/3788) of patients receiving TYGACIL and 3.0% (110/3646) of patients receiving comparator drugs. In a pooled analysis of these trials, based on a random effects model by trial weight, an adjusted risk difference of all-cause mortality was 0.6% (95% CI 0.1, 1.2) between TYGACIL and comparator-treated patients. The cause of this increase has not been established. This increase in all-cause mortality should be considered when selecting among treatment options [see Warnings and Precautions (5.4) and Adverse Reactions (6.1)].

(*Id.* ¶ 19.) The "Adverse Reactions" section of Tygacil's label was updated with similar information, also in July 2010. (*Id.* ¶ 20.)

On September 27, 2013, a "Black Box" warning was added to Tygacil's label, stating the following: "TYGACIL should be reserved for use in situations when alternative treatments are not suitable." (*Id.* ¶ 35.) A warning about Stevens-Johnson syndrome, among other information,

was also added to the Adverse Reactions section of Tygacil's label. (*Id.* ¶ 36.) Plaintiffs allege that Stevens-Johnson syndrome is a type of vasculitis. (*Id.* ¶ 37.)

Plaintiffs allege that Tygacil caused the injuries to Joyce described above. (*Id.* ¶ 34.) They contend that Defendants knew, or should have known, that Tygacil "unreasonably exposed patients to the risk of serious harm"; that Tygacil "was not safe for its intended purposes"; and that Tygacil would cause, and in some cases did cause, "serious medical problems" and "catastrophic injuries." (*Id.* ¶¶ 38–39, 42–44.) Plaintiffs also allege that Tygacil "continues to be marketed to the medical community and to patients as safer and more effective as compared to other competing products"; that Defendants have "underreported information about the propensity of [Tygacil] to cause injury and complications"; that Defendants "failed to perform proper and adequate" testing, research, follow-up studies, and analysis of post-marketing data "in order to determine and evaluate the risks and benefits of [Tygacil]"; that Defendants "provided incomplete and insufficient information to physicians . . . regarding the use of [Tygacil]"; and relatedly, that Defendants failed to provide "sufficient warnings" and "instructions" to put the general public, including Joyce, "on notice of the dangers and adverse effects caused by the use of [Tygacil]." (*Id.* ¶¶ 41, 46–50, 53, 56–57.)

II. Legal Standard

To survive a motion to dismiss under Federal Rule 12(b)(6), a complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). The standard of "facial plausibility" is met when "the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* Plausibility is distinct from probability, and "a well-pleaded complaint

may proceed even if it strikes a savvy judge that actual proof of the facts alleged is improbable, and that a recovery is very remote and unlikely." *Nielsen v. Rabin*, 746 F.3d 58, 62 (2d Cir. 2014) (quoting *Twombly*, 550 U.S. at 556) (internal brackets and quotation marks omitted). At the same time, a court is "not bound to accept as true a legal conclusion couched as a factual allegation." *Twombly*, 550 U.S. at 555 (internal quotation mark omitted). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 678.

III. Discussion

Plaintiffs assert ten causes of action against Defendants. Joyce brings claims for negligence, design defect, manufacturing defect, failure to warn, breach of express and implied warranties, fraud, and unjust enrichment, and Kermot brings a claim for loss of consortium. Plaintiffs also seek punitive damages. Defendants seek dismissal of Plaintiffs' claims on the grounds that the Complaint fails to plausibly allege medical causation and that the claims are otherwise insufficiently pleaded.

A. Choice of Law

There is a dispute at the outset as to which state's law governs Plaintiffs' claims. Plaintiffs take the position that New York law applies (*see* Dkt. No. 7, Plaintiffs' Memorandum of Law in Opposition to Defendants' Motion to Dismiss ("Opp. Memo"), at 8–9), while Defendants argue that Georgia law governs (*see* Dkt. No. 6, Defendants' Memorandum of Law in Support of Motion to Dismiss ("Def. Memo"), at 5 n.3; Dkt. No. 8, Defendants' Reply in Support of Motion to Dismiss ("Reply Memo"), at 8–10.)

"A federal trial court sitting in diversity jurisdiction must apply the law of the forum state to determine the choice-of-law." *Fieger v. Pitney Bowes Credit Corp.*, 251 F.3d 386, 393 (2d

Cir. 2001) (citing *Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 497 (1941)). In New York, the first step in the analysis is to determine whether there is an "actual conflict of laws." *Curley v. AMR Corp.*, 153 F.3d 5, 12 (2d Cir. 1998). Only if there is such a conflict is the court required to apply choice-of-law principles and resolve which state's law applies. *Fed. Ins. Co. v. Am. Home Assur. Co.*, 639 F.3d 557, 566 (2d Cir. 2011).

Defendants argue that the law of Georgia diverges from that of New York for at least several of Plaintiffs' claims, namely, design defect, comparative negligence, express warranty, and punitive damages. (Reply Memo at 8–9.) Neither party addresses whether there are conflicts of laws as to Plaintiffs' other claims. But the Court need not decide on this motion whether any conflicts exist. Georgia law clearly governs the contract claims and the tort claims that implicate conduct-regulating rules. And while it is unclear whether Georgia also supplies the law for loss-allocating rules, no conflicts in those rules are presented on this motion. The Court therefore need not address at this stage which state's law applies to loss-allocating rules.

"New York applies separate choice-of-law approaches to contract and to tort claims." *Fin. One Pub. Co. v. Lehman Bros. Special Fin., Inc.*, 414 F.3d 325, 336 (2d Cir. 2005). For contract claims, New York courts apply "the 'center of gravity' or 'grouping of contacts' choice of law theory." *Id.* (quoting *In re Allstate Ins. Co.*, 613 N.E.2d 936, 939 (N.Y. 1993)) (brackets omitted). The most significant contacts in this analysis are "the place of contracting, negotiation and performance; the location of the subject matter of the contract; and the domicile of the contracting parties." *Travelers Cas. & Sur. Co. v. Dormitory Auth.-State of New York*, No. 07-CV-6915 (DLC), 2008 WL 5233691, at *2 (S.D.N.Y. Dec. 16, 2008) (quoting *In re Allstate*, 613 N.E.2d at 940).

Georgia law governs Plaintiffs' two contract-based claims, namely, breach of express and implied warranty.[3] The center of gravity of these claims is Georgia. That is where the Tygacil was prescribed, purchased, and administered.[4] Georgia is where Defendants made alleged representations about the safety and fitness of Tygacil, where Joyce and her physicians allegedly relied on these representations in their decisions to use or prescribe Tygacil, and where Joyce was allegedly injured as a result of her reliance. Georgia is also Plaintiffs' domicile. Georgia law therefore clearly applies to the contract claims.

The analysis of the tort claims is somewhat more complicated. New York law requires application of an "interest analysis" to ascertain the applicable law for tort claims. *GlobalNet Financial.Com, Inc. v. Frank Crystal & Co.*, 449 F.3d 377, 384 (2d Cir. 2006) (quoting *Schultz v. Boy Scouts of Am., Inc.*, 480 N.E.2d 679, 684 (N.Y. 1985)) (internal quotation marks omitted). The analysis differs based on whether the law at issue is a "conduct-regulating" rule, *i.e.*, a rule that "people use as a guide to governing their primary conduct," or a "loss-allocating" rule, *i.e.*, a

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[3] New York recognizes breach of express and implied warranties as contractual claims. *See CBS Inc. v. Ziff-Davis Pub. Co.*, 553 N.E.2d 997, 1001 (N.Y. 1990) (noting "the prevailing perception of an action for breach of express warranty as one that is no longer grounded in tort, but essentially in contract"); *Denny v. Ford Motor Co.*, 662 N.E.2d 730, 734 (N.Y. 1995) (differentiating the strict products liability "tort remedy" from "the contractually based breach of implied warranty remedy").

The Court treats Plaintiffs' unjust enrichment claim as one based in tort. District courts in this circuit disagree about how to analyze unjust enrichment claims for choice of law purposes. *See Gerloff v. Hostetter Schneider Realty*, No. 12-CV-9404 (LGS), 2014 WL 1099814, at *9 (S.D.N.Y. Mar. 20, 2014). Here, Plaintiffs allege that Defendants were unjustly enriched at Plaintiffs' expense by means of Defendants' "fraud and other conscious and intentional wrongdoing." (Compl. ¶ 111.) The unjust enrichment claim here therefore appears to sound more in tort than it does in contract, and the Court treats it as such in the choice of law analysis. *Cf. Fieger*, 251 F.3d at 394 (applying the "center of gravity" test to a quantum meruit claim "sound[ing] more in contract than in tort").

[4] As noted above, the Complaint states that Plaintiffs were residents of Georgia at all relevant times. (Compl. ¶ 1.)

rule that "prohibit[s], assign[s], or limit[s] liability after the tort occurs." *Licci ex rel. Licci v. Lebanese Canadian Bank, SAL*, 672 F.3d 155, 158 (2d Cir. 2012) ("*Licci I*") (internal quotation marks omitted). Where, as here, the relevant rule is conduct-regulating, "the law of the jurisdiction where the tort occurred will generally apply because that jurisdiction has the greatest interest in regulating behavior within its borders." *Id.*

This motion presents the same issue that the Second Circuit confronted in *Licci*: which law applies when there is a conflict between the conduct-regulating rules in the place of the allegedly tortious conduct, on one hand, and the place of injury, on the other.[5] In *Licci*, the plaintiffs were civilians who were injured, or whose family members were injured or killed, in Israel by rocket attacks launched by Hizballah, a Lebanese terrorist organization, in 2006. *Id.* at 156. They brought claims against American Express Bank ("AmEx") and the Lebanese Canadian Bank ("LCB"), alleging that LCB maintained bank accounts for an alleged Hizballah affiliate and conducted wire transfers on behalf of the affiliate using its correspondent bank account at AmEx in New York. *Id.* The plaintiffs argued that Israeli law applied to their claims. *Id.* at 157.

The Second Circuit disagreed, concluding that New York had the greatest interest in the litigation. It found that all of AmEx's allegedly tortious conduct occurred in New York, where AmEx is headquartered and administers its banking correspondent services. *Id.* at 158. The court explained that, though the alleged injuries occurred in Israel, that factor did not govern where "the conflict pertains to a conduct-regulating rule." *Id.* The court accordingly concluded

[5] Again, the determination that Georgia law governs does not necessarily apply to conflicts of loss-allocating rules, which are not presented on this motion to dismiss but may arise at a later stage in the litigation.

"that New York, not Israel, has the stronger interest in regulating the conduct of New York–based banks operating in New York." *Id.*

The Second Circuit expanded on its reasoning in a subsequent opinion in the same case. *See Licci ex rel. Licci v. Lebanese Canadian Bank, SAL*, 739 F.3d 45 (2d Cir. 2013) ("*Licci II*"). The court made explicit its disagreement with intermediate state appellate courts that had read the Court of Appeals' decision in *Schultz*, 480 N.E.2d 679, to stand for the proposition that where a conflict arises between the laws of the place of the allegedly wrongful conduct and the place of injury, the latter generally controls. On a proper reading of *Schultz*, the court explained, where these laws diverge "it is the place of the allegedly wrongful conduct that generally has superior interests in protecting the reasonable expectations of the parties who relied on the laws of that place to govern their primary conduct and in the admonitory effect that applying its law will have on similar conduct in the future." *Licci II*, 739 F.3d at 50–51 (quoting *Schultz*, 480 N.E.2d at 684–85) (brackets and internal quotation marks omitted).

Here, some tort claims are premised on allegedly tortious conduct in New York, while others are based on conduct in Georgia. For the latter set of claims—fraud and unjust enrichment—Georgia law applies. Georgia is the place of injury and the place of Defendants' alleged tortious conduct that underlies both these claims, namely, fraudulent misrepresentations regarding the safety and quality of Tygacil.

Georgia law also applies to claims for which the tortious conduct occurred exclusively or largely outside Georgia: negligence, design defect, manufacturing defect, and failure to warn. The Complaint alleges that Defendants are headquartered in New York, and that they designed

and manufactured Tygacil there. (Compl. ¶¶ 7, 9.)[6] But even under *Licci*, that alone does not compel the conclusion that New York's law applies to these tort claims. *Licci* eschewed a bright-line rule for conflicts between conduct-regulating rules in the place of the tort and the place of the injury. On the contrary, the court reiterated that interest analysis is a "flexible approach" that aims to give effect to the law of the jurisdiction with "the greatest concern with the specific issue raised in the litigation." *Licci I*, 672 F.3d at 158 (internal quotation marks omitted). Here, Georgia has a legitimate and powerful interest in ensuring the safety of pharmaceuticals that out-of-state corporations market, sell, and distribute within its state to its own citizens. Moreover, application of Georgian law accords with the reasonable expectation of both parties: the location of the alleged injury here was not a mere fortuity, but the result of Defendants' deliberate efforts to sell Tygacil to physicians and consumers in Georgia. As the court in *Doe v. Hyland Therapeutics Div.*, 807 F. Supp. 1117, 1131 n.16 (S.D.N.Y. 1992), put it:

> Where rules of product liability are involved, we think the forum where the products are sold and consumed has the predominant interest in implementing the rules that form the basis for the "reasonable expectation of the parties" involved. . . . [F]rom the perspective of influencing primary conduct, the forum where the product is sold is uniquely qualified to determine the controlling standards that reflect an equilibrium between its need for the product, and its desire to deter the sale of potentially harmful products to its citizens.

Accordingly, even assuming that there is a conflict between the laws of Georgia and New York with respect to Plaintiffs' claims, the choice of law analysis points to the application of Georgia law.[7]

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[6] It is unclear from the Complaint whether Tygacil was designed or manufactured exclusively or even primarily in New York, but the Court shall assume so for purposes of the choice of law analysis.

[7] Recent cases involving product liability claims against out-of-state drug manufacturers support this conclusion. *See, e.g.*, *DiBartolo v. Abbott Labs.*, 914 F. Supp. 2d 601, 610 (S.D.N.Y. 2012) ("Here, [the plaintiff] is a resident of New York, was prescribed [the drug] in New York, purchased and used [the drug] in New York, and suffered injury in New York. It therefore

B. Medical Causation

Defendants seek dismissal of all of Plaintiffs' claims on the ground that they have failed to adequately plead medical causation. They argue that Plaintiffs have not fulfilled their obligation at the pleading stage to allege sufficient facts to draw the inference that Tygacil caused Plaintiffs' injuries.

This argument is unmeritorious. Plaintiffs' allegation that Joyce's use of Tygacil caused her injuries, including vasculitis, is facially plausible and well pleaded. Plaintiffs plead that, shortly after Joyce received Tygacil infusions for her abdominal infection, she developed certain serious and otherwise unexplainable medical conditions. Temporal proximity, combined with the absence of an alternative explanation, is sufficient to raise a reasonable inference that Tygacil is the cause of Joyce's injuries and permits the Complaint to withstand the motion to dismiss.[8]

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appears that New York has the strongest interest in this case."); *In re Zyprexa Prods. Liab. Litig.*, 277 F.R.D. 243, 249 (E.D.N.Y. 2011) (finding that Rhode Island was "the only state with a legitimate interest in the resolution of [the] litigation" because the plaintiff "was prescribed [the drug] in Rhode Island, all of his known physicians practice in that state, and he was hospitalized there"), *aff'd sub nom. Greaves v. Eli Lilly & Co.*, 503 F. App'x 70 (2d Cir. 2012).

[8] Plaintiffs have pleaded, moreover, that Stevens-Johnson syndrome—added to the "Adverse Reactions" section of Tygacil's label in 2013—is a form of vasculitis. (Compl. ¶¶ 36–37.) Defendants contend that Stevens-Johnson syndrome is "a different malady from the one [Joyce] allegedly suffered," (Def. Memo at 7), but give the Court no basis upon which to conclude that the matter is not subject to reasonable dispute and is therefore one of which judicial notice may be taken, *see Kramer v. Time Warner Inc.*, 937 F.2d 767, 773 (2d Cir. 1991) ("Of course, [a district court] may also consider matters of which judicial notice may be taken under Fed. R. Evid. 201 [on a motion to dismiss]."); Fed. R. Evid. 201(b) ("The court may judicially notice a fact that is not subject to reasonable dispute because it: (1) is generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.").

Defendants also contend that, even assuming that Stevens-Johnson syndrome is a form of vasculitis, "[p]ost-marketing events reported in the Adverse Reactions section of the label are based on individual case reports, and it is widely recognized that case reports are insufficient to establish causation." (Def. Memo at 7.) Whether or not that is so, it goes to *establishing*

The argument that Plaintiffs have failed to establish, through medical literature or otherwise, that Tygacil was the certain or even likely cause of Joyce's injuries is premature and appropriately raised on summary judgment or at trial.[9] Simply put, Plaintiffs' causation allegations are not implausible, and *Iqbal* and *Twombly* do not compel otherwise. Defendants' motion to dismiss on this ground is accordingly denied.

C. The Failure to Warn Claims

In a similar vein, Defendants argue that Plaintiffs' negligence- and strict liability–based failure to warn claims merit dismissal "because there are no factual allegations sufficient to establish that the risk of vasculitis was a known risk of which defendants had a duty to warn." (Def. Memo at 8.) This argument also fails.

In Georgia, "[a] claim for negligent failure to warn exists separately from strict liability claims." *Bryant v. Hoffmann-La Roche, Inc.*, 585 S.E.2d 723, 730 n.6 (Ga. Ct. App. 2003). But whether asserted in negligence or strict liability, a failure to warn claim has the same elements: a plaintiff must show, or at this stage allege, that a defendant had a duty to warn the plaintiff, that

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causation, not *pleading* it. The argument is therefore properly raised on summary judgment or at trial, not on a motion to dismiss.

[9] Defendants cite as "illustrative" the decision in *Gonzalez v. Bayer Healthcare Pharm., Inc.*, 930 F. Supp. 2d 808 (S.D. Tex. 2013). (Def. Memo at 6-7.) The plaintiff there alleged that an intrauterine contraceptive device ("IUD") manufactured by Bayer and implanted in her caused her to suffer from several serious medical conditions, including lupus. *Id.* at 816. The court dismissed most of the action under Federal Rule 12(b)(6). *Id.* at 821. Relevant here was the court's dismissal of the plaintiff's failure to warn claim because she had not alleged sufficient facts to show that the warnings were inadequate or that this inadequacy caused her injuries. *Id.* at 820–21. The court emphasized that the plaintiff had not identified or cited "any medical literature on the subject" or "allege[d] any other facts showing how or why Bayer knew or should have known of the risks of the contraceptive causing autoimmune reactions." *Id.* at 821. To the extent that *Gonzalez* requires a plaintiff asserting a failure to warn claim to plead such facts in order to survive a motion to dismiss, the Court disagrees with its interpretation of Federal Rule 12(b)(6).

it breached that duty, and that the breach proximately caused the plaintiff's injury. *See Dietz v. Smithkline Beecham Corp.*, 598 F.3d 812, 815 (11th Cir. 2010) (product liability failure-to-warn claim); *Wheeler v. Novartis Pharm. Corp.*, 944 F. Supp. 2d 1344, 1353 (S.D. Ga. 2013) (negligent failure-to-warn claim); *see also* Georgia Products Liability Law § 8:1 (4th ed. 2015) ("As a matter of pure jurisprudence, Georgia has traditionally recognized failure to warn claims arising both in negligence and in strict liability. As a practical matter, however, Georgia courts make no distinction between the two, but apply the same duty concepts and the same tripartite test of foreseeability of use, danger and user's knowledge." (footnotes omitted)).

"The duty to warn an end user of a risk associated with product use arises when the manufacturer knows or reasonably should know of a danger arising from product use." *Wheeler*, 944 F. Supp. 2d at 1353 (citing *Chrysler Corp. v. Batten*, 450 S.E.2d 208, 211 (Ga. 1994)). A defendant breaches that duty when it fails to either "adequately communicate the warning to the ultimate user" or "provide an adequate warning of the product's potential risks." *Schmidt v. C.R. Bard, Inc.*, No. 6:14-CV-62, 2014 WL 5149175, at *5 (S.D. Ga. Oct. 14, 2014) (quoting *Thornton v. E.I. Du Pont De Nemours & Co.*, 22 F.3d 284, 289 (11th Cir. 1994)) (internal quotation marks omitted).

Defendants contend that Plaintiffs' failure to warn claims are insufficiently pleaded because the Complaint contains no allegation that any other individuals using Tygacil developed vasculitis or that Defendants' knew of these individuals, or that there is any medical literature on the subject. (Def. Memo at 9.) But Plaintiffs need not so allege at this stage. They have adequately pleaded causation between Tygacil and Joyce's injuries, as noted above. It is not implausible, then, that Defendants knew or should have known about the potential for Tygacil to bring about these injuries, and that the warnings they provided failed to adequately communicate

the extent of that risk.[10] In other words, the Complaint's well-pleaded factual allegations give rise to a reasonable inference that Defendants acted tortiously in failing to warn Plaintiffs about the risks of using Tygacil. The motion to dismiss the failure to warn claims is therefore denied.

D. Design Defect

Plaintiffs also assert design defect claims in negligence and strict liability. They contend, based on Plaintiffs' injuries, that Tygacil is defective and poses an unreasonable risk of harm to consumers. (Compl. ¶¶ 60, 64.) Defendants maintain that these claims should be dismissed because "they do not allege any facts capable of supporting a conclusion that the risk posed by [Tygacil] outweighed its utility." (Def. Memo at 10.)

As it does with failure to warn claims, Georgia law distinguishes design defect claims in negligence from those in strict liability. *Banks v. ICI Americas, Inc.*, 450 S.E.2d 671, 674 n.3 (Ga. 1994); *see also Williams v. Web Packaging Corp.*, No. 5:97-CV-179-3 (DF), 2002 WL 389158, at *3 (M.D. Ga. Mar. 12, 2002) (noting that the distinction between negligence and strict liability in design defect cases must "matter to an extent"). But the analyses of these claims "generally will overlap." *Banks*, 450 S.E.2d at 674 n.3. Specifically, in both contexts the court will apply a risk-utility analysis to assess defectiveness; that is, the "product design is defective if the risks inherent in the design outweigh the utility or benefit derived from the product." *Bryant v. BGHA, Inc.*, 9 F. Supp. 3d 1374, 1383 (M.D. Ga. Mar. 27, 2014); *see also* Georgia Products Liability Law § 7:1 (4th ed. 2015) ("The risk-utility balancing test applies to all design defect

[10] Defendants contend, *contra* the Complaint, that the Adverse Reactions label was in fact updated to include Stevens-Johnson syndrome in 2011, before the Tygacil was administered to Joyce. (Def. Memo at 1–2.) The Court declines Defendants' invitation to take judicial notice of a document on the FDA website showing that to be so, because even if Defendants were correct, that fact alone would not necessarily be fatal to Plaintiffs' claim. It may be the case, for example, that even the updated label failed to provide an adequate warning of the alleged risks associated with Tygacil.

claims whether labeled as negligence or strict liability."). Several factors figure in the risk-utility test, but the "heart" of the analysis is about "whether the design chosen was a reasonable one from among the feasible choices of which the manufacturer was aware or should have been aware." *Bryant*, 9 F. Supp. 3d at 1383 (quoting *Banks*, 450 S.E.2d at 674) (internal quotation marks omitted).

Defendants contend that the design defect claims should be dismissed because Plaintiffs have failed to address the utility of Tygacil or the availability of better alternatives. (Def. Memo at 11.) But that argument "misconceive[s] what Plaintiff[s] must plead to weather a Rule 12(b)(6) motion and what Georgia's risk-utility analysis requires." *Schmidt*, 2014 WL 5149175, at *3 (denying motion to dismiss design defect claim where defendants claimed that plaintiff had failed to allege a safer alternative to defendants' product). At this stage, Plaintiffs must merely "set forth sufficient facts from which the Court can reasonably infer that the design was defective." *Id.*; *see also Frazier v. Mylan Inc.*, 911 F. Supp. 2d 1285, 1297 (N.D. Ga. 2012) (concluding that plaintiff had made out "a prima facie case for design defect" even though she did not identify a feasible alternative design for the drug). Plaintiffs have done so. They have plausibly alleged that Tygacil brought about Joyce's injuries. The Court may reasonably draw the inference from the Complaint that Tygacil—a drug that is designed to treat certain kinds of infections but allegedly caused severe vasculitis, organ damage, and full-body lesions, among other conditions—is legally defective under a risk-utility analysis. Plaintiffs have accordingly met their pleading burden, and Defendants' motion to dismiss the design defect claims is denied.

E. Manufacturing Defect

Plaintiffs also assert a manufacturing defect claim in strict liability. They allege that the Tygacil administered to Joyce "was not reasonably safe for its intended use" and was defective

"with respect to its manufacture." (Compl. ¶ 72.) Defendants seek dismissal of the claim because Plaintiffs have not alleged that the Tygacil "deviated from the product's design specifications." (Def. Memo at 12.) Plaintiffs' theory, Defendants argue, is instead "that the entire product line of [Tygacil] is unreasonably dangerous." (*Id.*)

This argument is without merit. A plaintiff asserting a product defect claim in strict liability, including a manufacturing defect claim, must allege that "(1) the defendant manufactured the allegedly defective product; (2) the allegedly defective product was not merchantable and reasonably suited for its intended use when the defendant sold it; and (3) the allegedly defective product proximately caused the plaintiff's injuries." *Edwards v. Wisconsin Pharmacal Co., LLC*, 987 F. Supp. 2d 1340, 1345 (N.D. Ga. 2013) (citing *Chi. Hardware & Fixture Co. v. Letterman,* 510 S.E.2d 875, 877–78 (Ga. Ct. App. 1999)). Plaintiffs have done this. They allege that Defendants manufactured the Tygacil prescribed and administered to Joyce; that this batch of Tygacil was not reasonably safe for its intended purpose; and that the defect proximately caused Joyce's injuries. Plaintiffs are not required, at the pleading stage, to identify precisely how the defective product deviated from normal specifications. *See id.* at 1345–46 (rejecting defendants' argument that plaintiff's manufacturing defect claim warranted dismissal because plaintiff did not "allege any specific manufacturing defect" or "describe how the product is defective" (internal quotation marks omitted)). And there is nothing inconsistent in pleading claims for both design defect and manufacturing defect: a plaintiff is permitted to advance alternative theories of liability for a defendant's allegedly wrongful conduct. *Kruse v. Wells Fargo Home Mortg., Inc.*, 383 F.3d 49, 55 n.3 (2d Cir. 2004) ("Federal Rule of Civil Procedure 8(e)(2) permits pleading inconsistent theories in the alternative."). Defendants' motion to dismiss the manufacturing defect claim is therefore denied.

F. Breach of Warranty[11]

Plaintiffs also bring claims for breach of express and implied warranty. They allege that "Defendants made assurances to the general public, hospitals and health care professionals that [Tygacil] was safe and reasonably fit for its intended purpose," and that Joyce, individually and/or through her physicians, relied on both these express warranties and implied warranties of merchantability in deciding to use or prescribe Tygacil. (Compl. ¶¶ 90, 92.) Defendants argue that the absence of privity between Plaintiffs and Defendants is fatal to the breach of warranty claims.

"Under Georgia law, to recover for a breach of warranty, a plaintiff must show privity between himself and the defendant." *Wheeler*, 944 F. Supp. 2d at 1354; *see also Lee v. Mylan Inc.*, 806 F. Supp. 2d 1320, 1325–26 (M.D. Ga. 2011) ("Georgia law still generally precludes the ultimate consumer from recovering on any express or implied warranty when the manufacturer sells the product to the original consumer."); *Andrews v. RAM Med., Inc.*, No. 7:11-CV-147 (HL), 2012 WL 1358495, at *3 (M.D. Ga. Apr. 19, 2012) (same). Privity with a consumer is deemed to exist "[i]f the manufacturer expressly warrants to the ultimate consumer that the product will perform in a certain way or that it meets particular standards." *Lee*, 806 F. Supp. 2d at 1326; *Cline v. Advanced Neuromodulation Sys., Inc.*, 17 F. Supp. 3d 1275, 1280 (N.D. Ga. 2014) (same); Georgia Products Liability Law § 4:2 (4th ed. 2015) (same).

The Complaint does not allege privity between Plaintiffs and Defendants. Nor does it allege that Defendants made express warranties to Joyce that the Tygacil was safe and would

[11] Plaintiffs fail to respond to Defendants' motion to dismiss as to the claims for breach of warranty, fraud, and unjust enrichment. They have accordingly abandoned these claims. *See Bonilla v. Smithfield Associates LLC*, No. 09-CV-1549 (DC), 2009 WL 4457304, at *4 (S.D.N.Y. Dec. 4, 2009) (Chin, J.). Nonetheless, out of an abundance of caution, the Court addresses the sufficiency of the Complaint as to these claims below.

work as intended; rather, it states that Defendants made such assurances merely to "the general public, hospitals and health care professionals." Defendants' motion to dismiss the breach of warranty claims is accordingly granted.[12]

G. Fraud

Plaintiffs allege that Defendants' conduct gives rise to a fraud claim. They argue that Defendants "falsely and fraudulently represented to [Joyce], her physicians, her surgeons, and to members of the general public that [Tygacil] was safe, effective, reliable, consistent, and better than the other antibiotics when used in the manner intended by the manufacturer." (Compl. ¶ 104.) These representations, Plaintiffs allege, induced Joyce to use Tygacil. (*Id.* ¶ 106.) Defendants move to dismiss the fraud claim on the basis that the Complaint does not identify any particular misrepresentation by Defendants regarding Tygacil.

The Court agrees that Plaintiffs' fraud claim is insufficiently pleaded. To make out a fraud claim under Georgia law, a plaintiff must plead that the defendant made false representations to the plaintiff, with the intent or purpose to deceive the plaintiff, and that the plaintiff was injured as a result of justifiable reliance on these representations. *Greenwald v. Odom*, 723 S.E.2d 305, 312 (Ga. Ct. App. 2012). But Federal Rule 9(b) sets a heightened pleading standard for fraud claims, requiring that plaintiffs "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). To survive a motion to dismiss, the plaintiff must "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the

[12] Because the Court grants the motion to dismiss on this ground, it need not address Defendants' argument that Plaintiffs' breach of express warranty claim fails because Plaintiffs "have not identified any particular affirmation of fact or promise capable of giving rise to an actionable express warranty." (Def. Memo at 14.)

statements were fraudulent." *U.S. ex rel. Kester v. Novartis Pharm. Corp.*, 23 F. Supp. 3d 242, 251–52 (S.D.N.Y. 2014) (quoting *Rombach v. Chang*, 355 F.3d 164, 170–71 (2d Cir. 2004)).

The Complaint falls short of the Rule 9(b) standard. The Complaint makes general allegations about false and fraudulent representations regarding the safety of efficacy of Tygacil, but fails to identify specific fraudulent statements, the particular speaker(s), or the place and date of any such statements. The motion to dismiss this claim is granted.

H. Unjust Enrichment

Finally, Plaintiffs assert an unjust enrichment claim against Defendants. They allege that, as a result of their "fraud and other conscious and intentional wrongdoing," Defendants succeeded in selling the Tygacil and were unjustly enriched accordingly. (Compl. ¶¶ 110–11.)

"A claim for unjust enrichment is not a tort, but an alternative theory of recovery if a contract claim fails. The theory of unjust enrichment applies when there is no legal contract and when there has been a benefit conferred which would result in an unjust enrichment unless compensated." *WESI, LLC v. Compass Envtl., Inc.*, 509 F. Supp. 2d 1353, 1363 (N.D. Ga. 2007) (quoting *Tidikis v. Network for Med. Comms. & Research, LLC*, 619 S.E.2d 481, 485 (Ga. Ct. App. 2005)) (brackets and internal quotation marks omitted). But here, the basis for the alleged unjust enrichment claim is Defendants' fraudulent conduct. Plaintiffs cannot avoid the heightened pleading requirement of Federal Rule 9(b) by casting their fraud claim as one for unjust enrichment. "To the extent any of Plaintiffs' claims are premised on fraudulent conduct, the facts alleging that conduct are subjected to the higher pleading standard of Rule 9(b)." *Welch v. TD Ameritrade Holding Corp.*, No. 07-CV-6904 (RJS), 2009 WL 2356131, at *22 (S.D.N.Y. July 27, 2009) (brackets and internal quotation marks omitted); *Abraham v. Am. Home Mortg. Servicing, Inc.,* 947 F. Supp. 2d 222, 230 (E.D.N.Y. 2013) (holding that Rule 9(b) applies to

"fraud-based claims," including unjust enrichment). Defendants' motion to dismiss this claim is granted.

IV. Conclusion[13]

For the foregoing reasons, Defendants' motion to dismiss is GRANTED IN PART and DENIED IN PART.

Plaintiffs seek to leave to file an amended complaint. That motion is GRANTED. Plaintiffs shall file their amended complaint, if any, within 14 days of the date of this opinion.

The Clerk of Court is directed to close the motion at docket number 5.

SO ORDERED.

Dated: May 1, 2015
New York, New York

J. PAUL OETKEN
United States District Judge

[13] Because some of Plaintiffs' main claims survive, their derivative claims for loss of consortium and punitive damages survive as well.

Defendants also seek dismissal of the punitive damages claim on the basis that the Complaint's allegations are insufficient to establish the willful and malicious conduct necessary to justify punitive damages. (Def. Memo at 18 n.8) Plaintiffs' well-pleaded allegations do not preclude the reasonable inference that Defendants engaged in such misconduct. The argument is accordingly properly resolved on summary judgment or at trial. Defendants' motion to dismiss on this ground is denied.